THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte IRA N. TARGOFF and QUN GE

Appeal No. 1996-1281
Application 07/945,295

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and ROBINSON, Administrative Patent Judges.

ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 11-15 and 26, which are all of the claims pending in this application.

Claims 11 and 26 are illustrative of the subject matter on appeal and read as

follows:

11. An isolated protein comprising a sequence of amino acids that includes all or a portion of the sequence of amino acids of the human Mi-2 antigen, wherein said portion includes at least one epitope of said antigen, and said protein is isolated by specific immunoreaction with an autoantibody present in human sera, which is immunoreactive with the human Mi-2 protein having the amino acid sequence set forth in Sequence ID No. 2.

26. An isolated protein comprising a sequence of amino acids that includes all or portion of the sequence of amino acids of PM-Scl antigen, wherein said portion includes at least one epitope of said antigen, and said protein is isolated by specific immunoreaction with an autoantibody present in human sera, which is immunoreactive with the human PM-Scl protein having the amino acid sequence set forth in Sequence ID No. 4.

The reference relied upon by the examiner is:

Targoff et al. (Targoff), "The Association between Mi-2 Antibodies and Dermatomyositis," Arthritis and Rheumatism, vol. 78 (7), pgs. 796-802 (1985).

Grounds of rejection

Claims 11 - 15 and 26 stand rejected under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the invention.

Claims 11-13 stand rejected under 35 U.S.C. § 102(b) or, alternatively, under 35 U.S.C. § 103. As evidence of anticipation/obviousness, the examiner relies on Targoff.

We reverse the rejection of the claims under 35 U.S.C. § 112, second paragraph and vacate the rejection made alternatively under 35 U.S.C. § 102(b) or 35 U.S.C. § 103.

Background

The invention, as presently claimed, is described at pages 1, 2, and 7 of the

specification as relating to human antigens associated with certain autoimmune pathogenesis including inflammatory myopathies polymyositis and polymyositis-scleroderma overlap, which are characterized by chronic muscle inflammation and proximal muscle weakness in patients. These antigens are designated Mi-2 antigen and PMScl antigen and are stated to be useful in diagnostic assays and as tools for studying autoimmune myositis.

Discussion

The rejection under 35 U.S.C. § 112, second paragraph

In a new ground of rejection raised in the Examiner's Answer (Answer), the examiner has rejected claims 11 - 15 and 26 stating (Answer, paragraph bridging pages 6-7):

> [I]t is not clear if the claimed isolated protein is to have the sequence as set forth in SEQ ID NO. 2 or can have that sequence as well as other amino acid residue sequences so long as the isolated protein contains at least one portion of the amino acid residue sequence of the human Mi-2 protein which has the amino acid residue sequence as set forth wherein said "portion" includes at least one epitope. The basis for this confusion seems to stem for [sic, from] the varying uses of titles to identify the protein and the antigen.

We have considered the arguments of both the examiner and the appellants relating to this rejection and find we are in agreement with the appellants that the rejection is improper. We, therefore, reverse the rejection under 35 U.S.C. § 112, second paragraph, and adopt appellants' reasoning at page 3 of the Reply to Examiner's Answer as our own.

The rejection under 35 U.S.C. § 102(b)/103

In rejecting claims 11-13 under 35 U.S.C. § 102(b) or, alternatively, under 35 U.S.C. § 103, the examiner relies on Targoff as teaching an isolated Mi-2 protein derived from calf thymus which binds to human autoantibodies, identified as "anti-Mi-2" antibodies, to human Mi-2 proteins. The examiner's position appears to be that the protein of the reference is encompassed by claim 11 since it is described as being immunogenically reactive with a human anti-Mi-2 antibody. The examiner concludes that this protein must inherently include at least one epitope as required by claim 11, and, thus, must inherently include at least a portion of the amino acid sequence of the SEQ ID NO. 2. (Answer, page 5). In explaining the obviousness aspect of the rejection, the examiner merely argues that it would have been obvious to have used the human autoantibodies which are immunoreactive with the Mi-2 antigen, as taught by Targoff, to isolate the protein which contains at least one epitope of human Mi-2 antigen. (Answer, page 6).

We have reviewed both the examiner's rejection and appellants' rebuttal arguments and evidence. However, on this record we do not find that the issues, as presented, permit a meaningful review. In arguing their respective positions on the issues raised by the rejection of claims 11-13 over Targoff, it does not appear that either the examiner or appellants have considered the most relevant legal standard appropriate for consideration of the facts presented in this appeal. Additionally, we note

the examiner's failure to address the material presented in Example 3 beginning at page 24 of the Specification which appellants urge constitutes a comparison of the bovine and human antigens presented. (Principal Brief, page 13). We are left with no indication as to whether the examiner failed to consider this evidence or found it unpersuasive and if unpersuasive the basis for that determination. We, therefore, vacate the rejection of claims 11-13 over Targoff and remand the application to the examiner for further consideration of the claims in this application in view of the remarks which follow.

Having reversed the rejection of claims 11-15 and 26 under 35 U.S.C. § 112, second paragraph, and vacated the rejection of claims 11-13 under 35 U.S.C. § 102(b) or, alternatively, under 35 U.S.C. § 103, all claims presently in this case are free of rejection.

Other Issues

Upon return of the application to the examiner, we would urge the examiner to step back and consider anew the patentability of at least claim 11. The question presented by this appeal is whether the bovine Mi-2 antigen disclosed by Targoff falls within the scope of claim 11. However, before this can be determined, it must first be ascertained just what is claimed. In making a patentability determination, "[a]nalysis begins with a key legal question -- what is the invention claimed?" since "[c]laim interpretation . . . will normally control the remainder of the decisional process," Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1567-68, 1 USPQ2d 1593, 1597 (Fed. Cir.), cert. denied, 481 U.S. 1052 (1987).

There appears to be confusion on the part of both the examiner and appellants as to just what is encompassed by the claims presently on appeal. We note for example the examiner's statements which would suggest that a protein falling within the scope of claim 11 would need to have only a portion of the amino acid sequence of human Mi-2 antigen (SEQ ID NO. 2.) (Answer, page 2). The examiner also suggests that while the isolated protein must be specifically immunoreactive with an autoantibody that binds specifically with human Mi-2 antigen, this does not limit the site of binding to only that portion which has the same amino acid residue sequence which is shared with human Mi-2 protein. (Id). Similarly, the appellants have argued that the claims are directed to human Mi-2 antigen. (Principal Brief, page 13). It is not clear what language in claim 11 would limit the claimed isolated protein to the human antigen. Further, in responding to the rejection under 35 U.S.C. § 112, second paragraph, appellants have stated:

> it is clear that the protein could have sequence other than the sequence set forth in Sequence ID No. 2, so long as a portion of the protein had a sufficient portion of the sequence set forth in Sequence ID No. 2 to be immunoreactive.

Thus it falls to both the examiner and appellants to begin the consideration of the issues raised by Targoff with a determination as to just what is being claimed.

In our view, the claims can reasonably be interpreted in at least two ways. The first interpretation would find that the claim is directed to a protein which includes within its amino acid sequence the whole or portion of the amino acid sequence of SEQ ID NO. 2. The second interpretation would find that the claim is directed to a protein of

undefined sequence, which includes at least one epitope, also of undefined sequence, which would result in the protein being immunoreactive with an autoantibody present in human sera where said antibody is immunoreactive with the protein having the amino acid sequence set forth in SEQ ID NO. 2. It should be clear that the second interpretation results in a claim of broader scope. A review of both the examiner's and appellants' position as presented in this appeal would suggest the importance of determining just what is encompassed by the claims. We leave to the examiner and appellants the determination of the appropriate interpretations. Only after it is determined what is encompassed by the claim, can one make the informed decision whether the bovine Mi-2 antigen described by Targoff is reasonably encompassed by the claim.

Having determined what is claimed, then the examiner is in the position to determine whether the proteins described by Targoff can reasonably be said to fall within the scope of claim 11. The examiner bears the initial burden of presenting a prima facie case of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. Id. In reconsidering the patentability of the claims in this application we would urge the examiner to consider the principles set forth in In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977) and In re Swinehart, 439 F.2d 210, 212, 169 USPQ 226, 228-29 (CCPA 1971) which provide that where the claimed and prior art products reasonably appear to be identical or substantially identical, the PTO can require an applicant to show that the

prior art products do not necessarily or inherently possess the characteristics of his claimed product. We do not intend to suggest that the examiner can only meet this burden by presenting prior art which includes both the amino acid sequence and the nucleotide sequence which would encode a particular protein. It is sufficient if the examiner presents evidence which would reasonably establish that the product of the reference reasonably appears to be identical or substantially identical with the claimed product. Should the examiner determine that the protein disclosed by Targoff reasonably appears to fall within the scope of claim 11, the examiner should also weigh the evidence represented by the comparison of the bovine protein with the human protein which the appellants urge is present in Example 3 at page 24 of the specification.

Should it be determined, having weighed all of the evidence, that the claims are properly rejectable under either 35 U.S.C. § 102 or 35 U.S.C. § 103, the examiner should then issue an appropriate office action setting forth the basis for the rejection and provide appellants with the appropriate opportunity to respond.

CONCLUSION

The examiner's rejection of claim 11-15 and 26 under 35 U.S.C. § 112, second paragraph, is reversed.

The examiner's rejection of claims 11-13 under 35 U.S.C. § 102(b), or alternatively, under 35 U.S.C. § 103 is vacated.

REVERSED

SHERMAN D. WINTERS Administrative Patent Judge	)	
WILLIAM F. SMITH Administrative Patent Judge	)	) BOARD OF PATENT APPEALS AND INTERFERENCES
DOUGLAS W. ROBINSON Administrative Patent Judge	)	

Patrea L. Pabst
Arnall, Golden & Gregory
2800 One Atlantic Center
1201 W. Peachtree Street
Atlantic, GA 30309-3400

dwr/ki